



PATENT  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: William D. Thomas, Jr. et al. Art Unit: Not Yet Assigned

Serial No.: 10/737,270 Examiner: Not Yet Assigned

Filed: December 16, 2003 Customer No.: 21559

Title: Passive Immunization Against Clostridium Difficle Disease

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449. The references listed on the Form PTO-1449 were submitted to and/or cited by the Office in the prior application and, therefore, copies of these references are not provided for this application

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this statement an admission that the information is material to patentability.

This statement is being filed within three months of the filing date of the application.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: January 20, 2004

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SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Attorney Docket No.	06132/045004		
		INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Serial No.	10/737,270		
				Applicant	William D. Thomas Jr. et al.		
(37 C.F.R. §1.98(b))				Filing Date	December 16, 2003		
				Group	Not Yet Assigned		
				IDS Filed	January 23, 2004		
<b>U.S. PATENTS</b>							
Examiner's Initials	Patent Number	Issue Date	Patentee		Class	Subclass	Filing Date (If Appropriate)
	5,412,077	05/02/95	Siber et al.				
	5,530,103	06/25/96	Gristina et al.				
	5,582,827	12/10/96	Siber et al.				
	5,599,539	02/04/97	Carroll et al.				
	5,601,823	02/11/97	Williams et al.				
	5,762,934	06/09/98	Williams et al.				
	5,773,000	06/30/98	Bostwick et al.				
<b>FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION</b>							
Examiner's Initials	Document Number	Publication Date	Country or Patent Office		Class	Subclass	Translation (Yes/No)
	WO 94/13264	06/23/94	PCT				
	WO 96/07430	03/14/96	PCT				
	WO 96/12802	05/02/96	PCT				
	WO 97/02836	01/30/97	PCT				
<b>OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)</b>							
	Allo et al., "Prevention of Clindamycin-Induced Colitis in Hamsters by <i>Clostridium sordelli</i> Antitoxin," <i>Gastroenterology</i> 76:351-355 (1979).						
	Corthier et al., "Protection against Experimental Pseudomembranous Colitis in Gnotobiotic Mice by Use of Monoclonal Antibodies Against <i>Clostridium difficile</i> Toxin A," <i>Infection and Immunity</i> 59:1192-1195 (1991).						
	Fekety et al., "Diagnosis and Treatment of <i>Clostridium difficile</i> Colitis," <i>Journal of the American Medical Association</i> 269:71-75 (1993).						
	Fernie et al., "Active and Passive Immunization to Protect Against Antibiotic Associated Caecitis in Hamsters," <i>Dev. Biol. Stand.</i> 53:325-332 (1983).						
EXAMINER			DATE CONSIDERED				
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.							



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SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	
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OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)			
Johnston, "Antibody Responses to Clostridial Infection in Humans," <i>Clinical Infectious Diseases</i> 25:2 S173-177 (1997).			
Johnson et al., "Systemic and Mucosal Antibody Responses to Toxin A in Patients Infected with Clostridium difficile," <i>Journal of Infectious Diseases</i> 166:1287-1294 (1992).			
Kelly et al., "Anti-Clostridium difficile Bovine Immunoglobulin Concentrate Inhibits Cytotoxicity and Enterotoxicity of C. difficile Toxins," <i>AntiMicrobial Agents and Chemotherapy</i> 40:373-379 (1996).			
Kim et al., "Immunization of Adult Hamsters against Clostridium difficile-Associated Ileocecalitis and Transfer of Proteciton to Infant Hamsters," <i>Infection and Immunity</i> 55:2984-2992 (1987).			
Kyne et al., "Prospects for a vaccine for Clostridium difficile," <i>BioDrugs</i> 10:173-181 (1998).			
Leung et al., "Treatment with Intravenously Administered Gamma Globulin of Chronic Relapsing Colitis Induced by Clostridium difficile Toxin," <i>The Journal of Pediatrics</i> 118:633-637 (1991).			
Libby et al., "Effects of the Two Toxins of Clostridium difficile and Immunological Comparison of the Toxins by Cross-Neutralization Studies," <i>Infection and Immunity</i> 36:822-829 (1982).			
Libby et al., "Production of Antitoxins of Two Toxins of Clostridium difficile and immunological Comparison of the Toxins by Cross-Neutralization Studies," <i>Infection and Immunity</i> 35:374-376 (1982).			
Lyerly et al., "Passive Immunization of Hamsters Against Disease Caused by Clostridium difficile by use of Bovine Immunoglobulin G Concentrate," <i>Infection and Immunity</i> 59:2215-2218 (1991).			
Lyerly et al., "Vaccination Against Lethal Clostridium difficile Enterocolitis with a Nontoxic Recombinant Peptide of Toxin A," <i>Current Microbiology</i> 21:29-32 (1990).			
Mitty et al., "Clostridium difficile Diarrhea: Pathogenesis, Epidemiology, and Treatment," <i>The Gastroenterologist</i> 2:61-69 (1994).			
Mulligan et al., "Elevated Levels of Serum Immunoglobulins in Asymptomatic Carriers of Clostridium difficile," <i>Clinic of Infectious Diseases Suppl</i> 4:S239-244 (1993).			
Salcedo et al., "Intravenous Immunoglobulin Therapy for Severe Clostridium difficile Colitis," <i>Gut</i> 41:366-370 (1997).			
Torres et al., "Clostridium difficile Vaccine: Influence of Different Adjuvants and Routes of Immunization on Protective Immunity in Hamsters," <i>Vaccine Research</i> 5:149-162 (1996).			
Torres et al., "Evaluation of Formalin-Inactivated Clostridium difficile Vaccines Administered by Parenteral and Mucosal Routes of Immunization in Hamsters," <i>Infection and Immunity</i> 63:4619-4627 (1995).			
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